

Annualized Biostatistics Effort Allocation Guidelines^{1,2}				
Project	Large/complex projects	Regular projects	Simple projects	Limited scope projects³
Total Effort	50-100% + per year	30-65% per year	20-35% per year	< 10% per year
PhD Effort	20% + per year	10-15% per year	5-<10% per year	Hourly/Re-charge ³ per year
MS Effort	30-100% + per year	20-50% per year	10-25% per year	5-<10% or hourly ³ per year
Activity Scope	<p>Large or complex projects that require a high level of involvement in development and implementation of the project and communication of study results. Involvement may take many forms, including any of the following:</p> <ul style="list-style-type: none"> • Development and/or implementation of complex study designs. • Assembly of datasets from large, complex or poorly documented sources (e.g. administrative or survey databases). • Development and/or implementation of interim data analyses during data collection phase of prospective studies. • Development of and/or use and interpretation of novel or complex statistical methods. • Developing algorithms to identify units of analysis and define analysis variables • Active participation in publications, with opportunity for first authored papers. 	<p>Projects with standard study designs and routine analyses. Involvement includes:</p> <ul style="list-style-type: none"> • Collaboration through all phases of the study, including the biostatisticians attending regular study meetings. • Involvement of biostatisticians in study design, implementation, and data collection. • Well-documented primary datasets provided for statistical analysis • Analyses carried out using off-the-shelf procedures available in statistical software packages. • Active participation in publications, with opportunity for first authored papers. 	<p>This profile is appropriate for simple projects requiring minimal PhD biostatistician collaboration and straightforward statistical analyses performed by an MS biostatistician. Involvement is limited to:</p> <ul style="list-style-type: none"> • Occasional meetings with PI about study issues, such as choice of statistical methods to use. This level of effort is typically too low for a PhD-level biostatistician to carry out analyses or support weekly meeting attendance. • This level of effort for the PhD biostatistician is generally not compatible with smooth workflows and readily available collaborative support, unless an <i>experienced and capable</i> MS biostatistician is adequately supported on the project. • Assistance planning and conducting early Phase I trials (e.g. adaptive trials) with active monitoring. • Feedback from the biostatisticians on 1-2 manuscripts. 	<p>Occasionally, a limited amount of funding may be justified to support research needs that may include the following:</p> <ul style="list-style-type: none"> • Assistance planning routine, small early-Phase trials with little monitoring, or modest proof-of-concept animal studies • Small studies with limited scope requiring minimal statistical analysis. • Feedback or advice on a project in which oversight/monitoring is not necessary.
Example	A research group with multiple R01s, an NIH P or U, or over 500K R01s, such as large, prospective cohort studies or trials that also include substantial retrospective or record data collection.	Most R01s with proposed study design and statistical methods that statisticians would consider standard or routine.	Smaller scope R-level grants, such as R21s or R34s.	Work on a consultation basis, such as for smaller foundation grants, or R level grants in the basic sciences for which data analysis is not the biostatistician's responsibility.

¹Adopted from University of California Davis School of Medicine *Guidelines for Estimating Biostatistician Effort and Resource Guidelines on Grants*. Drafted and revised by Nichole Carlson (Univ of Colorado, Denver), Jody Ciolino (Northwestern), Gina-Maria Pomann (Duke), Sandra Taylor (Univ of California, Davis), and Leah Welty (Northwestern) with feedback from members of the Division of Biostatistics, Northwestern University Feinberg School of Medicine as well as members of the Biostatistics, Epidemiology, and Research Design Special Interest Group within the Association for Clinical and Translational Science.

² Effort allocation guidelines assume that other necessary other resources such as research study coordinators and project coordinators are also included in the budget. If a project has a strong research study coordinator or team of coordinators, it may be possible for biostatistics effort to be on the lower end of the range provided (e.g., if project coordinator sets up and maintains the study database with limited input from the biostatisticians). Notably, biostatistics effort does not include data entry.

³ Very small projects may budget for biostatistics support using the approved recharge rate in place of personnel effort. Please discuss these unique situations with the biostatistician to determine the appropriate effort level and/or recharge rate.